

Better **Safe** Than Sorry

Look inward, not just overseas,
to **prevent product safety** mishaps

by Randall L. Goodden

In 50 Words Or Less

- The product recalls of 2007 weren't just the result of out-of-control overseas suppliers.
- Many problems originated in the product design stage before suppliers got involved.
- Companies must analyze hazards and risks associated with developing and releasing products, but many aren't informed or don't fully comprehend this specialized area.

LAST YEAR'S RECORD number of product recalls, especially recalls of children's toys, drew worldwide attention to product safety and defective products. The recall stories topped newscasts and made headlines in newspapers coast to coast. Recall concerns quickly spread through Europe, Australia, Canada, Malaysia, Japan and elsewhere. By year's end, concern for product safety and import control had become a serious concern around the globe.



**WARNING
NO LIFEGUARD
ON DUTY**

In the United States, the Consumer Product Safety Commission (CPSC) spearheaded 473 recalls involving 110 million products in 2007, the largest number of recalls in 10 years.¹ Although media attention focused on children's toys and "Made in China" labels (especially around the Christmas season), recalled toys actually amounted to less than half the total consumer products recalled by the CPSC.² Even though other product types were recalled more often—household, outdoor, sports and recreational, and specialty items—nothing drew as much attention as the toy recalls.

With the toy recalls, the CPSC issued warnings about potential hazards of lead paint, choking, swallowing, cuts and strangulation. For the recalled household products, the CPSC was concerned about fire, shock, burn and carbon monoxide poisoning hazards. The various sports and recreational products were recalled because of hazards related to falls, fires, burn-

ing, drowning and loss of control.³

In addition to the 473 CPSC warnings, there were countless other recalls in 2007:

- Nearly 400 drug, food and pet food recalls handled by the Food and Drug Administration.
- Millions of pounds of beef and other food products recalled by the Department of Agriculture.
- Almost 600 motor vehicle related recalls handled by the National Highway Traffic Safety Administration.
- Miscellaneous recalls issued by the Environmental Protection Agency, the U.S. Coast Guard and other commercial companies not controlled or recorded by government agencies.

Some manufacturers received substantial fines for their defective products. In fact, the CPSC issued \$2.75 million worth of fines and penalties to companies for failure to initially report a hazardous condition.⁴

PRODUCT SAFETY, LIABILITY PROTECTION

Product safety and liability prevention involve more than just warning labels, defective designs and engineering concerns. It involves many areas of business and many, if not all, areas of management. To effectively limit the possibility of problems, everyone needs to understand what a company could face.

Contracts and agreements: Does your company have sound contracts and agreements in place to help limit its potential exposure to product liability? These could be between your company and suppliers, dealers, manufacturing reps, service companies or even their customers. Remember, if there aren't safeguards to shield your company from a negligent supplier of a component part, you could be in store for the same amount of trouble as you would have had the component originated with your company.

Product design reviews: The design review is the first critical step in a product's life cycle and the least expensive time to recognize a potential problem

and make changes. After all, design defects can be far more devastating than manufacturing defects. Do you have design review and product safety teams that review all new products to ensure quality, reliability and manufacturability? Do the teams ensure the product will be dependable, safe and reliable, not only for its intended use and application, but

“ Do your people know what to do if the testing produces unfavorable results? ”

also in cases of foreseeable misuse? Do the teams generate meeting minutes?

Product safety reviews: Does the company maintain a well-trained product safety team to handle the hazard analysis and risk assessments of all new products developed?

Marketing and advertising con-

cerns: It isn't just defective products that could lead to troubles, but the things you say to promote a product. For instance, images shown in promotional videos, brochures or packaging might send a specific message and could lead to a product liability lawsuit. Sales and marketing can sometimes push the envelope when promoting a product by overstating its features, benefits or capabilities. Do you know what such liabilities are, and what words and things to avoid?

Reliability testing: Does your company routinely test new products to ensure they're safe and reliable? Some companies lost major cases recently because of a lack of adequate testing. Even with such testing, do your people know what to do if the testing produces unfavorable results?

Warning labels and instructions: There are international standards for warning label design, as well as instructions. Are your engineers familiar with them? Are the labels and instructions you're using in compliance with

Exposure to **product liability** shouldn't rest with just the **engineering group.**

Some manufacturers—vitamin maker Leiner Health Products, Topps Meats and Foreign Tire Sales—were so overwhelmed by the recall expense that they went out of business or sought bankruptcy protection.⁵

Assigning blame

The vast amount of media attention pointed the finger at Chinese manufacturers as the culprits behind the defective products that were discovered in stores throughout the United States.

were largely at fault for the lead paint defect. But this defect represented less than half of the recalls involving children's products made in China.⁶

This brings to light some problems associated with overseas suppliers and the associated economies. Purchasing products or materials from untested or unproven suppliers in places such as China or India isn't the same as doing business with established suppliers in places such as Europe. For instance, depending on the supplier, if products are either defective or result

Most of the recalled products were made in China (the country in which 80% of toys and 40% of all consumer products that end up in the United States are produced), and Chinese manufacturers

these known standards?

Records retention programs:

Records will become critical to your defense in a product liability lawsuit. The court will demand many types of records in a short timeframe. Do you have a sound records retention program?

Document control: Once you produce the records demanded by the court, what would these documents say? Many product liability cases are lost and punitive damages awarded because the plaintiff can prove through the company's own records that it had prior knowledge of a problem or defective condition and failed to react in a responsible manner. Do you and your employees understand what could constitute a dangerous document?

Supplier selection and control: If your supplier manufactures faulty components, your company could be in as much trouble as it would have been had it made the components. Without proper safeguards, the company and supplier could be sued, even though the company might have been supplied defective components. From a legal

perspective, the more companies a plaintiff can name and sue in a lawsuit, the merrier—especially companies with deep pockets. Do you have adequate indemnification clauses in place? Do some of your smaller suppliers and subcontractors carry liability insurance? Does anyone in your purchasing group even ask?

Warranties: All products come with some sort of warranty, but does your sales and management team know the difference between full and limited warranties or express and implied warranties? That nicely printed warranty form might not be the only warranty you're going to be bound to, and your sales and management team probably doesn't even know it.

Recall procedures: Never wait for a disaster to determine how to initiate a recall. Are you recall ready? There are numerous ways to handle a potential recall or a field problem. If you're manufacturing consumer products, there are other reporting requirements you

must follow or you could face substantial fines. Do you have procedures for your management team to follow? Do you know who would be in control? Does that individual know the ways and means of conducting a recall, or are outside resources available?

Incident reports: Most product liability cases start as an incident being reported and grow to become lawsuits. Do your employees know how to handle such a notification of an incident? Do they know whom to contact in your company when they're made aware of a field incident, or do they just try to handle it themselves?

Accident investigation: If you investigate an accident or incident right from the start, you could successfully prevent a lawsuit and possibly get the other party to drop the issue altogether. If you have the tendency to just forward everything to your insurance company for it to handle, it is almost guaranteed you're going to take a loss. —R.G.



in injury or lawsuits and must be recalled from the market, the company that brought the products into the United States will bear all the costs and liabilities, regardless of any contractual agreements that might have been written.

The only protection for the U.S. importer is to require its overseas suppliers to hold insurance with an American international insurance company to cover any potential problems. Beyond that, U.S. retailers or manufacturers buying products from overseas suppliers must have a presence at those plants to ensure the product is being made to exact specifications.

Beyond just suppliers and lead paint

The majority of “Made in China” recalls were due to reasons other than lead paint. Defective designs were typically the fault of the companies that originally created the specifications and ordered the products from China and were not the fault of the Chinese companies contracted to manufacture the products.

This is part of a problem that plagues many manufacturers, not only across the United States, but also around the world:

- Design and engineering departments develop new products that contain design defects or safety hazards because they lack knowledge and training in the areas of hazard analysis and risk assessment.

- Unaware that the actual design might already be defective, quality departments step in and ensure the products are consistently made per specifications.

The concerted effort can eventually lead to massive recalls and product liability lawsuits.

Typically, most corporations believe they hold an above average knowledge of product safety issues and requirements, and their employees know what’s best to prevent such product safety issues from surfacing. Often, these optimistic beliefs fall well short of reality.

In many instances, the companies don’t even hold formal design reviews for their new products or conduct a thorough analysis by a product safety team. At best, the designer or engineer of record performs a biased failure mode effects analysis, which only scratches the surface.

Last year’s recalls weren’t just a supply chain problem. They were the result of the primary corporation failing in one of the following areas:

- Design reviews and product development.
- Product safety and hazards analysis efforts.
- Product testing.
- Supplier selection, inspection and control.
- In-process quality control.

Product safety and liability prevention is considered a specialized field that requires training to understand, and it encompasses a large number of concerns that

touch many departments in a corporation. This prevention requires an entire management team, not just the engineering group, to understand the ramifications.

Every company is susceptible

Whether it’s a commercial, industrial or consumer product, or a large or small manufacturer, there’s high potential risk with every new product launch. It’s surprising how ill-prepared many manufacturers can be in this area.

The size of the company is no indication of the level of knowledge or expertise on product safety and liability prevention in the company. You would assume this lack of expertise would be evident at only small companies with limited staff. But recent surveys of engineering groups and management teams

Components of prevention / FIGURE 1



There's **so much potential risk** riding on every new product launch. It's surprising **how ill-prepared many manufacturers** can be.

of large *Fortune* 500 companies show high percentages of management employees with a significant lack of knowledge in this area.⁷

In the best of situations, CEOs of companies would be out front on this issue and insist on developing this knowledge and expertise. In many situations, this effort is driven by quality management leaders.

But with knowledge and training, manufacturers could reduce the chances of problems and be in the best position to overcome any potential risks, such as recalls or lawsuits.

In some cases, a CEO might have a false sense of security about the company's abilities because of the company's comprehensive quality programs or certifications. One of the largest recalls and product liability disasters in the past eight years happened to one company that was QS-9000 and ISO 9002 certified. It cost that company and its supplier—Ford and Firestone—billions of dollars.

Quality programs don't offer much protection in this area. In fact, the programs might be a liability if documented audit records reveal the company isn't following its own procedures.

Engineers and others

CEOs might say they believe they have talented teams of design engineers. But it is quite common to find that many engineers and management personnel, especially as they get more experienced and feel more comfortable in their positions, never attend seminars or seek to further their knowledge in any given field.

Perhaps it's arrogance. The company unknowingly begins to digress as it no longer follows state-of-the-art design concepts and product safety innovations. This increases the company's own exposure to risk. The engineers and management personnel are the people the CEOs are banking on to develop the products of tomorrow and protect the future of the company.

Exposure to product liability shouldn't rest with just the engineering group. Actions, or lack of appropriate actions, by the management team (up through the executive ranks) can subject the company to product liability lawsuits. It can be a reason the company lost a lawsuit and was forced to pay hefty punitive damages (which, to their surprise, probably won't be covered by insurance).

When design engineers are the ones knowledgeable on product safety and liability prevention, these individuals will become enlightened in areas only they can control. But the rest of the organization won't gain any of the knowledge it must have. Engineers don't have power over corporate procedures that pertain to other functions.

To appreciate what this focus involves, you must understand the entire scope of product safety and liability prevention, shown in Figure 1. The sidebar, "Product Safety, Liability Protection," (pp. 30-31) details each component. Everyone must understand the potential issues and best practices and get on the same page. Members of management might begin to understand their specific roles to prevent the company from being hit with a product liability lawsuit.

Insurers, lawyers get involved

Major insurance companies around the world are seeking product safety and liability knowledge for their own representatives and in-house consultants, as well. As they learn the key elements of what manufacturing companies must have in place, they can use the information as a checklist to evaluate new manufacturing clients.

Some insurance carriers won't even insure manufacturers if they don't have a formalized recall program in place. For existing clients, initiating such product safety and liability programs can lead to reduced insurance premiums. Such programs can demonstrate that

the clients' operations pose less risk for the insurance carrier.

Leveraging your corporation's legal defense firm might not always be an effective alternative. Surprisingly, product liability prevention is not widely known or taught by lawyers or law firms. Lawyers know how

to defend a manufacturer in a product liability lawsuit, but most have limited knowledge of the inner workings of a manufacturing company, departmental roles and responsibilities, or how to incorporate such safeguards into procedures and processes.

In addition to preparing on the insurance and legal

fronts, there is much for manufacturing companies to learn and implement internally:

- Design review procedures.
- Product safety hazards analysis.
- Product testing and design validation.
- Protective contracts and agreements.
- Good supplier selection and control.
- Recall plans of action.

Until manufacturers become better prepared, expect to see news on massive recalls and devastating product liability lawsuits grab more and more headlines.

REFERENCES

1. Interviews with Richard O'Brien, director of the office of international programs and intergovernmental affairs at the Consumer Product Safety Commission (CPSC), and Scott Wolfson, CPSC spokesman.
2. CPSC website, www.cpsc.gov.
3. Ibid.
4. CPSC, "Performance and Accountability Report—Saving Lives and Keeping Families Safe," www.cpsc.gov/cpsc/pub/pubs/reports/2007par.pdf, November 2007, p. 4.
5. Andrea Chang, "Leiner Health Products Files for Bankruptcy Protection," *Los Angeles Times*, www.latimes.com/features/health/la-fi-leiner11mar11,1,4393383.story, March 11, 2008.
6. Lucy P. Allen, Renzo Comolli and Simona Heumann, "China Product Recalls: What's at Stake and What's Next," National Economic Research Associates, www.nera.com/image/pub_chinaproductrecalls_2.08_final.pdf, February 2008.
7. Goodden Enterprises LLC, product safety and liability seminar audience surveys, <http://rigooodden.tripod.com>.

© Randall L. Goodden, 2008.



RANDALL L. GOODDEN is the president of Goodden Enterprises LLC, a training and consulting firm based in Eagle, WI. He is the author of two books on product safety and liability, including *Product Liability Prevention—A Strategic Guide*, ASQ Quality Press, 2000. Goodden is an ASQ fellow and has served as chairman of ASQ's

product safety and liability prevention interest group for the last 10 years.

Reduce line stoppages and production delays



Introducing new special processes training ...

Understanding the Heat Treat System Assessment (CQI-9)

Understanding the Plating System Assessment (CQI-11)

Understanding the Coating System Assessment (CQI-12)

These original courses, from the developers of the corresponding AIAG guidelines, detail:

- What is required to complete a special process assessment
- How to determine objective evidence
- How to complete the cover sheet, the assessment and the job audit
- What is required in the process tables

If you are involved in the implementation, maintenance and/or compliance of heat treat, plating and/or coating assessments, you can't afford to miss these exclusive AIAG courses.



**Sign up today
by calling
(248) 358-3003
or visiting
www.aiag.org**